



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#18

Food and Drug Administration
Rockville MD 20857

Re: Optiray
Docket No. 89E-0055

OCT 6 1989

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OFFICE OF THE ASSISTANT
COMMISSIONER OF PATENTS

Charles E. Van Horn, Esq.
Deputy Solicitor, Solicitor's Office
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,396,589⁹⁸ filed by Mallinckrodt, Inc. under 35 U.S.C. 156. The patent claims the human drug product Optiray, New Drug Application 19-710.

In the April 4, 1989, issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). The notice provided that on or before October 2, 1989, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. FDA, therefore, considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: George R. Pepper
Bernard, Rothwell and Brown
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Washington, DC 20006